

OCT 17 2000

## 510(k) Summary

**1.0 Date Prepared**

October 13, 2000

**2.0 Submitter (Contact)**

Martin D. Sargent  
Regulatory Affairs Manager  
Medtronic Xomed  
Jacksonville, FL  
(904) 279-7586

**3.0 Device Name**

Proprietary Name:	XPS Nitro
Common Name(s):	Pneumatic surgical drill, mastoid drill, ENT drill, handpiece, accessories, and cutting burs
Classification Name(s):	Drill, surgical, ENT (electric or pneumatic) including handpiece

**4.0 Device Classification**

Classification Name: Drill, surgical, ENT (electric or pneumatic) including handpiece  
ProcCode: 77ERL      Class II      21 CFR § 874.4250

**5.0 Device Description**

The XPS Nitro system consists of a pneumatic hose, footswitch, and handpiece. The handpiece drives a variety of dissecting burs and drills. Various attachments are available to stabilize dissecting burs and provide irrigation. A twist drill attachment provides adjustable hole depth. The system may be connected to a hospital nitrogen supply or to a nitrogen tank via an optional regulator.

**6.0 Indications for Use**

The XPS Nitro is indicated for the incision and removal of soft and hard tissue or bone in general otorhinolaryngology, head and neck, and otoneurological procedures, including mastoidectomy and mastoidotomy.

## 510(k) Summary *(continued)*

### 7.0 Substantial Equivalence

The XPS Nitro is substantially equivalent to the Medtronic Xomed ACE drill system as described in K960853 in its intended use, function, and performance characteristics.

Characteristic	XPS Nitro (Proposed)	Xomed ACE (K960853)
Intended use	Controlled incision or removal of bone	Controlled incision or removal of bone
Maximum speed	65,000 RPM	70,000 RPM
Drill power	Pneumatic	Electrical
Footswitch type	Pneumatic speed control	Electrical speed control
Handpiece autoclavable	Yes	Yes
Handpiece flash autoclavable	Yes	Yes
Drill collet design	Collet designed for Xomed Notched burs	Collet designed for Xomed Notched burs
Bur irrigation available	Yes	Yes
Irrigant supply	Supplied by external pump	Supplied by integral pump on drill console



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

OCT 17 2000

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Martin D. Sargent  
Regulatory Affairs Manager  
Medtronic Xomed, Inc.  
6743 Southpoint Dr. North  
Jacksonville, FL 32216

Re: K002828  
Trade Name: XPS Nitro System  
Regulatory Class: II  
Product Code: 77 ERL  
Dated: September 8, 2000  
Received: September 11, 2000

Dear Mr. Sargent:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

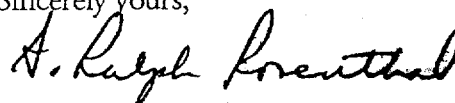
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Page 2 - Mr. Martin D. Sargent

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-6413. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in cursive script that reads "A. Ralph Rosenthal".

A. Ralph Rosenthal, M.D.  
Director  
Division of Ophthalmic and Ear,  
Nose and Throat Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

510(k) Number (if known): K002828

Device Name: XPS Nitro

Indications for Use:

The XPS Nitro is indicated for the incision and removal of soft and hard tissue or bone in general otorhinolaryngology, head and neck, and otoneurological procedures, including mastoidectomy and mastoidotomy.

(Please do not write below this line - continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Kenn Brhn  
(Division Sign-Off)  
Division of Ophthalmic Devices  
510(k) Number K002828

JS

Prescription Use ☒  
(Per 21 CFR 801.109)

Or

Over-the-Counter Use ☐

(Optional Format 1-2-96)